REMARKS

I. Preliminary Remarks

The Claims were subject to a Restriction Requirement, mailed March 9, 2006. Applicant chose Group I, Claims 1-11, 20-31 and 76-83, drawn to an immunogenic/vaccine composition. In the Office Action, the restriction requirement was made final. However, the claims that the Examiner stated are withdrawn (Claims 8-19, 28-75 and 80-82) and the claims examined (Claims 1-7, 20-27, 76-79 and 83) are in conflict with the claims included in Group I in the Restriction Requirement. Claims 8-11, 28-31, and 80-82 were included in Group I but were withdrawn in the Office Action. Applicant respectfully requests clarification of the claims that are withdrawn and those examined. Applicant believes that the claims in Group I as specified in the Restriction Requirement are the appropriate ones for examination.

After entry of this paper, Claims 3 and 22 are original. Claims 1-2, 4-11, 20-21, 23-31, and 76-83 are amended. Claims 12-19, and 32-75 are withdrawn, with claims 12, 18, 54, and 70-72 being withdrawn and amended. Withdrawn claims are withdrawn without prejudice in an effort to favorably advance prosecution of the present application. Applicant reserves the right to pursue the subject matter of the withdrawn claims in a continuation application, or to have the withdrawn claims rejoined in the current application. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below.

In this response, Applicant addresses each of the rejections raised by the Examiner. Applicant therefore respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 21-0718 for any fees necessary with the submission of this Response.

II. Patentability Arguments

A. The Rejection of Claims 5-6, 25-26, and 79 under 35 U.S.C. §112, Second Paragraph, May Properly Be Withdrawn.

Claims 5-6, 25-26, and 79 were rejected as containing the trademark/tradename *Amphigen*. Applicant respectfully traverses this rejection. Claims 5-6, 25-26, and 79 have been amended to replace the term 'Amphigen' with the term 'lecithin and oil blend' (see listing of claims above), which renders this rejection moot. Withdrawal of this rejection is therefore respectfully requested.

B. The Anticipation Rejection of Claims 1-2, 7, 20-21, and 76 under 35 U.S.C. §102(b) May Properly Be Withdrawn.

A patent is invalid for anticipation under 35 USC 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

Claims 1-2, 7, 20-21, and 76 are rejected under 35 U.S.C. §102(b) as being anticipated by Talens, et al., (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280).

Talens teaches a multivalent vaccine composition against BRD comprising IBR virus, PI3 virus, BRSV strains, an inactivated strain of BVD virus, and a bacterin comprising Leptospira serotypes and Campylobacter fetus, suitable for the induction of a protective immune response against said pathogens. Applicant respectfully submits that the subject matter of Claims 1, 20, and 76, as amended, differs from Talens in that the immunogenic composition of the instant invention comprises inactivated virus of two BVDV subtypes, types 1 and 2. Thus, Talens does not disclose each and every limitation of the invention as claimed. Accordingly, the subject matter of Claims 1, 20, and 76, and claims dependent therefrom, is not anticipated by Talens.

Claims 1-2, 7, 20-21, 27; and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Bowland, et al., (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48).

Bowland discloses commercial vaccines available in Canada for bovine respiratory disease. However, this reference displays a listing of vaccines which does not provide sufficient details of the vaccines to identically disclose each and every limitation of the invention as set forth in the claims. For example, Applicant respectfully submits that the subject matter of Claims 1, 20, and 76, as amended, differs from Bowland in that the immunogenic composition of the instant invention comprises inactivated virus of two BVDV subtypes, types 1 and 2. Thus, Bowland does not disclose each and every limitation of the invention as claimed. Accordingly, the subject matter of Claims 1, 20, and 76, and claims dependent therefrom, is not anticipated by Bowland.

Thus, based on the remarks presented herein, the rejection of Claims 1-2, 7, 20-21, 27, and 76 under 35 U.S.C. §102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

C. The Obviousness Rejection of Claims 1-7, 20-27, 76-79 and 83 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

Claims 1-7, 20-27, 76-79 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talens, et al., (Journal of the American Veterinary Medical Association, May 1, 1989, Vol. 194, No. 9, pages 1273-1280) or Bowland, et al., (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48) as applied to claims 1-2, 7, 20-21, 27; and 76, and further in view of Barr, et al., (Advanced Drug Delivery Reviews, 1998, Vol. 32, No. 3, pages 247-271), Pruette, et al., (Veterinary Parasitology, 1995, Vol. 58, No. 1-2, pages 143-153), and Wilson, et al., (Canadian Journal of Veterinary Research, Oct 1995, Vol. 59, No. 4, pages 299-305). Applicant respectfully traverses this rejection.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195

USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

As discussed in Section B above, neither Talens nor Bowland discloses or contemplates the instant invention. They do not teach or enable an immunogenic composition or a vaccine composition comprising a modified live Bovine Herpes Virus (BHV-1); a modified live parainfluenza virus Type 3 (PI3); a modified Bovine Respiratory Syncytial Virus (BRSV); an adjuvant; a Bovine Viral Diarrhea Virus Type-1 (BVDV-1); a Bovine Viral Diarrhea Virus Type-2 (BVDV-2); and a veterinary-acceptable carrier. As stated in the specification of the present application, modified-live virus (MLV) vaccines, on the other hand, offer a higher level of protection. Currently, licensed BVDV MLV vaccines are produced using attenuated viruses obtained via repeated passage in bovine or porcine cells or using chemically modified viruses which exhibit a temperature-sensitive phenotype. However, as these vaccines have been developed using type I BVDV virus strains, the protection is against type I virus only. Moreover, the available BVDV vaccines are not indicated for use in pregnant cattle or calves nursing pregnant cows.

Barr, et al., state that Quil A was found to be a be a heterogeneous mixture of saponins and that the existence of many different saponins, which vary in their chemical or biological activities, makes characterization of the material difficult and more importantly, may lead to unpredictable effects in vivo as a result of the variable content of the individual saponins in the mixture (see page 249, column 1). This teaches away from using Quil A adjuvants in the compositions of the present invention.

Pruette, et al., present data on the immunization of cattle with a composition comprising hypodermin A, a serine protease of the first-instar larva from the cattle grub *Hypoderma lineatum* and either Freund's complete adjuvant, alhydrogel, amphigen, or alhydrogel plus amphigen. The ingredients of the composition are very different than those claimed in the present application. For example, the antigen in the Pruette composition (hypodermin A, a serine protease purified from a homogenate of esophageal stage of the first-instar larva of the cattle grub *Hypoderma lineatum*) is different than the agents in the instant invention (see page 144, Materials and Methods). There is nothing in Pruette to

suggest that the adjuvants used in the cattle grub hypodermin A homogenate vaccine could be used successfully in the compositions of the present invention. There is no indication in Pruette that would suggest that the reference be combined with the other cited references.

Pruett, et al., in addition, provides conflicting teachings in that they state that Freund's complete adjuvant (CFA) is not acceptable for use in veterinary vaccines because of chronic inflammation and sterile abscessation at the injection site (see page 150, paragraph 2). HyA in combination with alhydrogel did not elicit a level of specific antibody in peripheral circulation comparable with the level elicited by HyA in combination with CFA (see page 150, paragraph 3). The alhydrogel formulation was ineffective at eliciting a strong cellular response (see page 151). Of the adjuvant formulations tested amphigen induced the least activity, both in terms of antibody concentration and delayed-type hypersensitivity (see page 151). Histamine release associated with the immediate reaction may have had negative affects upon lymphocyte function and chemotaxis (see page 151, paragraph 1). Thus, Pruette teaches away from using these adjuvants in the compositions of the present invention.

Wilson, et al., present data on the immunization of swine with a subunit of A. pleuropneumoniae in a composition containing an adjuvant. The ingredients of the composition are very different than those claimed in the present application. For example, the antigen in the Wilson composition (an anionic subunit prepared from a strain of A. pleuropneumoniae) is different than the agents in the instant invention (see page 300, column 1). There is nothing in Wilson to suggest that the adjuvants used in the swine subunit A. pleuropneumoniae vaccine could be used successfully in the compositions of the present invention. There is no indication in Wilson that would suggest that the reference be combined with the other cited references. Wilson also provides conflicting teachings in this matter. The results in Wilson indicate that some mineral oils resulted in severe tissue reactions (see page 299, column 1; page 302, columns 2 and 3; page 303, column 1). This teaches away from using mineral oils in the compositions of the present invention.

None of the references cited by the Examiner suggest Applicant's invention. In addition, Applicant respectfully submits that merely because the references can be combined, does not render the combination obvious. To support an obviousness rejection, the prior art must suggest the desirability of making the combination. *In re Fritch* (CAFC 1992) 972 F2d

1260, 23 PQ2d 1780. Before one determines that the prior art teaches one of ordinary skill in the art to make the changes necessary for the present invention, one must first determine that the prior art suggests that the references be combined. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* (CAFC 1989), 139 F3d 877, 45 PQ2d 1977. However, there is no indication in any of the references that would suggest they be combined, and thus there can be no reasonable expectation that such a combination would be successful. In fact, within the references there is teaching away from Applicant's invention. Only hindsight would allow the Examiner to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process.

The standard for obviousness is not combining what one can find in the prior art. It is inappropriate to use applicant's disclosure to assemble an argument. As discussed in *In re Papesch* (315 F.2d 318, 391, 137 USPQ 43, 51 CCPA 1963), "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing... There is no basis in the law for ignoring any property in making such a comparison" (based on the similarity of a compound's formula to the formula of another compound). Thus, it is inappropriate to ignore the properties that the Inventor of the current invention discovered.

Thus, although the Examiner states that "it would have been obvious to the person of ordinary skill in the art at the time the invention was made to add an adjuvant to the multi-viral and bacterial antigen vaccine for increased antibody response, less toxicity and lessened skin reaction" and "the person of ordinary skill in the art would have been motivated to make that (those) modification(s) because of the teachings of Barr and Pruette and reasonably would have expected success because of the adjuvant comparison results of Wilson" this is not the standard for obviousness. The MPEP (2143.01) teaches that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. However, there is no such suggestion in the references of the desirability of combining the references. As stated above, only hindsight has allowed the Examiner to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process.

The Applicant respectfully submits that none of the references cited by the Examiner suggest Applicant's invention. There is no indication in any of the references that would

suggest that the references be combined. Moreover, even when combined the references do not yield Applicant's invention. Accordingly, it is respectfully submitted that the immunogenic compositions and vaccine compositions, as presently claimed, are not rendered obvious by Talens, et al., or Bowland, et al., in view of Barr, et al., Pruette, et al., and Wilson, et al. Thus, based on the remarks presented herein, the rejection of Claims 1-7, 20-27, 76-79, and 83 under 35 U.S.C. §103(a) is overcome. Because none of the references, alone or in combination, teaches Applicant's invention, withdrawal of the rejection is respectfully requested.

III. Conclusion.

In view of the amendments and remarks made herein, Applicant respectfully submits that Claims 1-11, 20-31 and 76-83 are in condition for allowance and requests expedited notification of same.

Respectfully submitted,

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